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Date: 6/13/04 11:48AM
Subject: Comments of FR 04-7985

Dr. Vogl. I am submitting the following comments on the revised Guidelines lowering of the creatinine criterion for a "substituted" specimen:

Substitution testing and criteria have been controversial subjects over the past few years for regulated testing. Originally, HHS concluded, based on studies by HHS and the Department of Transportation, that the creatinine criterion of less than or equal to 5 mg/dL was appropriate; that it was very unlikely that employees could produce urine meeting that standard through physiological means.

Over two years ago, information evolved suggesting that the criteria for the treatment of substitution matters should be reconsidered. DOT became aware of a small number of cases in which individuals appear to have had legitimate medical explanations for producing specimens with a creatinine level of less than or equal to 5 mg/dL. These explanations have involved showings by a few individuals that they can produce low-creatinine specimens in demonstrations for a referral physician. Also, there was an increasing consensus among scientific and medical experts in relevant fields that the 5 mg/dL standard may not be appropriate for all people.

During February 4-6, 2003, information was presented and discussed at a conference sponsored by the DOT in Tampa, Florida,. Attendees at the conference (toxicologists, nephrologists and other physicians, MROs, technical experts in various fields, DOT and HHS officials) generally agreed that it would be appropriate to lower the creatinine criterion. The purpose of doing so would be to largely eliminate the possibility that individuals who could naturally produce urine creatinine concentrations below that current standard would be identified as having substituted a specimen.

DOT showed great leadership in this area by immediately issuing an Interim Final Rule on May 28, 2003, (68 FR 31624-27), which authorized Medical Review Officers to interpret "substituted" specimens using a lower criteria of 2 mg/dL. Now, when the MRO gets a report from the laboratory that the creatinine level in a specimen is greater than or equal to 2 mg/dL but less than or equal to 5 mg/dL, the MRO will report the specimen to the employer as "dilute," just as if the creatinine concentration were greater than or equal to 5 but less than 20 mg/dL (and also negative or positive, as provided in 49 CFR Part 40, §40.155). When the MRO gets a report from the laboratory that the creatinine level in a specimen is 2 mg/dL or above but less than or equal to 5 mg/dL, the MRO – in addition to reporting the specimen to the employer as dilute – must take an additional step. This step is to direct the employer to require the employee to undergo an immediate recollection under direct observation. The employer must then ensure that this recollection takes place.

I concur with the change to lower the creatinine criterion. In the interests of safety and in my role providing assistance to an MRO, I do like the interim change that DOT added –o to require a second collection. Approximately half of the specimens that my MRO ordered recollected come back positive. I must add that all of the positive recollections were males -- none for females.

Respectfully submitted,

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